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Randomized Trial in the Phillipines

PRINCIPAL INVESTIGATOR: Dr. D. M. Parkin

CONTRACTING ORGANIZATION: International Agency for Research on
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FOREWORD

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D.M. Park
PI - Signature

11/10/95
Date

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Introduction

Breast cancer (BC) accounts for 720,000 new cases per year and it is the most frequent cancer in women. Incidence rates are rising in many countries, particularly in the developing world. At present, our knowledge of environmental risk factors does not permit formulation of any practical primary prevention programs. Improvements in surgical techniques, or in radiotherapy, are very unlikely to provide more than marginal changes in mortality rates.

A much greater decrease in deaths from breast cancer is achievable through screening programs which lead to detection of cancers which are smaller, at an earlier stage, and less malignant than those which surface clinically. Several randomised trials of screening for breast cancer have been carried out; in the majority the screening modality used was mammography, with or without physical examination of the breasts. There is a clear consensus that such screening programs are capable of decreasing the risk of mortality from breast cancer (Miller *et al.* 1990; Day, 1991). In the Swedish two-country trial using single view mammography, screening every 30 months reduced breast cancer mortality by some 40% in screened women over the age of 50.

However, population screening programs which depend upon mammography require extensive provision of expensive technology and highly trained radiologists and radiographers. The cost per life-year saved is, therefore, relatively high (Barnum and Greenberg, 1991), and clearly an inappropriate use of health care resources for many countries (WHO, 1984). Furthermore, it seems that mammographic screening is relatively inefficient for women under the age of 50, either because their cancers are faster growing, or because the sensitivity of mammography in the pre-menopausal breast is relatively low.

The alternative screening strategies which have been proposed are physical examination of the breasts (PE), and breast self-examination (BSE). Researchers of the University of Washington are conducting a large scale trial of BSE among 300,000 textile workers in Shanghai, China. This trial is scheduled to last 9 years. PE has never been used as the sole modality of screening, so that its effectiveness is not known. However, indirect evidence based on estimates of the accuracy of PE relative to mammography suggests that this type of examination could reduce mortality rates by perhaps 2/3 to 3/4 of that achievable by mammographic screening in women aged 50 or more. PE alone may be effective in younger women, in whom mammographic screening has not yet demonstrated any benefit.

Purpose of the present work is to establish 1) whether a programme of mass screening by PE performed by trained paramedical personnel can be set up in a developing country as part of the routine activity of first level health services, and 2) whether and to what extent such a programme can reduce mortality from breast cancer. The location is the greater Manila area of the Philippines. This population has a relatively high incidence of breast cancer, considerably above other Asian populations, and comparable to that in southern Europe.

Body

The study is a randomised controlled trial of the effect of annual PE of the breasts performed by trained nurses/midwives, in reducing mortality from breast cancer. The units of randomisation are health centres (HCs) within municipalities of the Manila - Rizal area. Women aged 35 - 64 years who are resident in the intervention HC areas are invited for a total of 5 annual breast examinations, carried out by trained midwives/nurses. At the first visit, the women are instructed in the technique of breast self examination (BSE) and provided with a leaflet in the local language explaining the purpose and methodology of BSE. Reinforcement of BSE knowledge is given at subsequent visits.

The study area comprises the central more urbanised municipalities of the National Capital Region (Districts I, II, III and IV) which includes 12 municipalities each having municipal health centres in the township area and barangay health stations in more rural areas.

Health centres are allocated to intervention or control group by stratified random sampling to ensure equality by socio-economic status, as well as population size. The total female population at risk in each group is about 170,000.

Examiners are trained using a programme already developed and tested in the Philippines. Training is repeated every other year for the duration of the intervention. Women eligible for screening are invited to participate through a variety of mechanisms. A pilot study has demonstrated that a substantial proportion of eligible women will visit the health centre for other reasons ('walk-ins'), and this use is especially prevalent in areas of lower social class. 'Walk-in' subjects can also be used to recruit friends and neighbours. Those who are not contacted via these mechanisms are traced by home visits.

At the first visit, an interview is administered, recording demographic variables and risk factors for breast cancer. Instruction in BSE is given at this visit and PE performed. An attempt is made to interview subjects who do not wish to participate in the project; should they refuse interview, data on socio-economic status is recorded and a recommendation made for the subject to visit her preferred physician for annual breast examination.

Women with detected abnormalities are referred for final diagnosis to special clinics, made available in 3 major hospitals staffed by project personnel.

Results obtained during the first year of the project are as follows:

1. A coordinating centre has been set up at José Reyes Memorial Hospital, one of the referral centres for women detected with abnormalities. The necessary equipment has been purchased: computer, photocopy machine, car and Mammacare™ kits to train the nurses.
2. An IARC staff member has been recruited and briefed in Lyon about the project. She took up her duties in Manila at the beginning of July, coordinating full-time the project activity.
3. Two hundred and two HCs were randomly allocated to intervention and control groups.
4. The baseline questionnaire was developed, tested and finalised (appendix 1).
5. Nominative lists of eligible women by HC are being prepared and are almost complete.
6. Personnel from the staff of HC has been identified and trained to perform screening PE.
7. Hospital clinics for referral of positive women and mechanisms for documentation of results have been established (appendix 2)

Conclusions

The work done is in agreement and fits into the timing outlined in the project application for the first year activity.

Some changes to the original plan of work can now be anticipated concerning the training of field personnel. New administrative procedures which define the responsibilities and duties of the various bodies involved in administering health care, have been implemented by the Philippine Government. These imply a periodical substantial reshuffling of the field personnel between HCs. Therefore, personnel will need to be recruited and trained for the whole duration of the intervention.

As a consequence, sessions to evaluate the performance of the examiners may also need to be more frequent than originally planned.

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Miller, A.B., Chamberlain, J., Day, N.E., Hakama, M. and Prorok, P.C. (1990) Report on a workshop of the UICC project on evaluation of screening for cancer. *Int. J. Cancer* **46**, 761-769

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Appendix 1

Questionnaire administered at recruitment.

Text is available both in English and Tagalog languages.

BREAST CANCER SCREENING PROJECT - BASELINE QUESTIONNAIRE

DATE
day month yearPlace of visit 1=health centre 2=home 3=other, specify Examiner Record No from population lists Study ID number Family name Given name Age Date of birth
day month yearCurrent address House no: Street Street no Bgy Bgy no Municipality/Town/City City Code Province (if applicable) Province Type of house 1=cement 2=wood 3=makeshift Ownership of House 1=owned 2=rented 3=n/a (maid) Tel No if available

Name and address of closest relative (preferably in Manila)

Family name Given name Current address House no Street Street no Bgy Bgy no Municipality/Town/City City Code Province Province Type of house 1=cement 2=wood 3=makeshift

1 EDUCATION / EDUKASYON

- 1.1 Did you go to school?.....1=yes.....2=no.....☐
Nakapag-aral ho ba kayo?1=oo.....2=hindi

(If NO go to 2.1) (Kung HINDI ang sagot - itanong and 2.1)

- 1.2 How old were you when you finished your studies?.....age (yrs).....☐
Ilan taong gulang ho kayo nang matapos ninyo ang inyong pag-aaral?

- 1.3 Which was the highest level of study which you completed?.....☐
Ano ang pinakamataas na natapos ninyo sa pag-aaral?

0= no complete qualification

1=Primary

2=vocational (qualified manual worker)

3=Secondary

4=College

5=Post-graduate

0=hindi nakatapos ng elementarya

1=Elementaria

2=Vocational (Skilled)

3=High School

4=Kolehiyo

5=Mataas pa sa kolehiyo

2 INCOME / KITA NG PAMILYA

- 2.1 What is your family's average monthly income in pesos?.....☐
Ano ang buwanang kita ng inyong buong pamilya? (pesos)
- 2.2 How many families live in your house?☐
- 2.3 How many cohabitants is your family composed of (include yourself)?.....☐
Ilan tao ang nakatira sa inyon bahay na umaasa sa iyo?

3 TOEACCO SMOKING / PANINIGARILYO

- 3.1 Have you ever been a regular smoker?.....1=yes.....2=no.....☐
(at least one cigarette a day for 6 months at any time in your life)
Ikaw ba ay regular naninigarilyo sa inyong buhay?.....1=oo.....2=hindi

(if NO, never smoker, go to 4.1) (Kung HINDI regular naninigarilyo, Itanong and 4.1)

- 3.2 What age were you when you began to smoke regularly?.....☐
Ilan taong gulang kayo noon una kayong regular na nanigarilyo ng isa or higit sa isang sigarilyo sa isang araw?

- 3.3 Do you still smoke?.....1=yes.....2=no.....☐
Naninigarilyo pa ba kayo?.....1=oo.....2=hindi

- 3.3.1 If NO, what age were you when you stopped?.....☐
Kung HINDI, Ilan taong gulang kayo noong huminto kayong manigarilyo?

- 3.4 For how many years did you smoke/have you been a smoker?.....☐
Ilang taon kyaong nanigarilyo/naninigarilyo?

- 3.5 How many cigarettes per day did you used to smoke/do you smoke?
(record the number of cigarettes per day of the longest period).....☐
Ilang sigarilyo ang nauubos ninyo sa isang araw?
(Kung regular kang naninigarilyo, ilan ang nambos mo sa isang araw)

4 ALCOHOL DRINKING / PAG-INOM NG ALAK

- 4.1 Do you drink alcoholic beverages?.....1=yes.....2=no.....☐
 Umiinom ba kayo ng alak?.....1=oo.....2=hindi

(If NO, go to 5.1) (Kung HINDI ang sagot - itanong ang 5.1)

- 4.2 If YES, do you drink almost every day or only occasionally?
 Kung OO, umiinom ba kayo araw-araw
 1=nearly every day.....2=occasionally.....☐
 1=halos araw-araw 2=minsang lang

5 REPRODUCTIVE HISTORY / PANGANGANAK

- 5.1 How old were you when you first menstruated?.....☐☐
 Ilan taong gulang ho ba kayo noong una kayong niregla?

- 5.2 Are you still menstruating?.....1=yes.....2=no.....3=Do not know.....☐
 Nireregla pa ba kayo?1=oo.....2=hindi.....3=hindi ko alam

- 5.3 When did you have your last menstruation? Complete date if known.....☐☐☐☐☐☐
 Kailan ho ba kayo huling niregla? day month year
 days ago ☐☐ Ilang araw na ang nakakaraan
 months ago ☐☐ Ilang buwan na ang nakakaraan
 years ago ☐☐ Ilang taon na ang nakakaraan or/o
 age ☐☐ Ilan taong gulang ho ba kayo noong huli ninyong regla?

- 5.4 If no menstruation in the last 12 months, what was the cause of menstrual cessation?
 Kung hindi na kayo nireregla sa loob ng labing-dalawang buwan, bakit hindi?
 1=natural 1=natural na huminto
 2=surgical 2=inoperahan sa matris/obaryo
 3=following radiation 3=na-radiotherapy
 4=pregnancy 4=nabuntis.....☐

- 5.4.1 If surgical, do you know whether both your ovaries were removed?
 Kung kayo'y inoperahan, alam ba ninyo kung tinanggal and dalawang obaryo?
 1=both removed 1=parehong tinanggal
 2=only one 2=isa lang
 3=do not know 3=hindi ko alam
 4=only hysterectomy, no ovaries removed
 4=hysterectomy lamang, walang obaryong tinanggal.....☐

- 5.5 Have you ever been pregnant?.....1=yes.....2=no.....☐
 Nagdala'tao ho na ba kayo?1=oo.....2=hindi

(If NO, go to 5.5.1) (Kung HINDI, itanong ang 5.5.1)

- 5.5.1 How old were you when you first got pregnant?.....☐☐
 Ilan taong gulang ho kayo noong una kayong nabuntis?

- 5.5.2 How old were you when your first child was born? (0=no live births).....☐☐
 Ilan taong gulang ho ba kayo noong ipinanganak ninyo ang inyong panganay?
 (0=walang pinanganak na buhay)

- 5.5.3 How old were you when your last child was born? (0=no live births).....☐☐
 Ilan taong gulang ho ba kayo noong ipinanganak ninyo ang inyong buso?
 (0=walang pinanganak na buhay)

5.5.4 How many of the following have you had? (0=none).....

Sa karanasan ninyo, ilan sa mga sumusunod ang naranasan ninyo?

Full term pregnancies (include live and stillbirths)..... | |

Pag-anak pagkatapos ng siyam na buwan (buhay/patay)

Spontaneous miscarriages..... | |

Pagbuntis na kusang nalaglag

Induced abortions..... | |

Pagbuntis na ipinalaglag

If MENOPAUSAL, go to 5.7 Kung Kayo'y MENOPAUSE na sa 5.7

5.6.1 Are you currently pregnant?.....1=yes.....2=no.....3=Maybe..... | |
Nagpapasuso ho ba kayo ngayon?.....1=oo2=hindi.....3=Malamang

5.6.2 Are you breast feeding.....1=yes.....2=no..... | |
Kayo ho ba ay nagpapasuso?.....1=oo.....2=hindi

5.7 Have you ever used any contraceptive methods?.....1=yes.....2=no..... | |
Gumagamit na ba kayo ng pagkontra sa pabubuntis?.....1=oo.....2=hindi
Make sure that the interviewee knows what a contraceptive is
Seguraduhing alam ng pasyente ang ibig sabihin ng kontraseptibo

(If NO, go to 6.1) (Kung HINDI ang sagot - Itanong ang 6.1)

Which of the following contraceptive methods have you ever used?

Ano sa mga sumusunod na pagkontra sa pagbubuntis ang ginamit o ginagamit ninyo sa inyong buhay?

5.7.1 Oral contraceptive..... age when first used | |
Tabletang kontraseptibo o pill Gulang noong unang gumamit

age when last used | |

Gulang noong huling gumamit

Last brand used, name _____

Pangalan ng pinakahuling tabletang ginamit o ginagamit _____

5.7.2 Injectable contraceptive..... age at first injection | |
Ineksiyong kontraseptibo Gulang noong unang gumamit

age at last | |

Gulang noong huling gumamit

5.7.3 Sterilization by tubal ligation..... age at intervention | |
May tale ang tubo ng matris (tubal ligation) Gulang noong nagpatale

5.7.4 Other,specify (cumulative code)..... | |
Ibang klaseng kontraspetibo (summa total)

1=Condom

2= Diaphragm

4=IUD

8=periodic abstinence or rhythm/o pag-didiyeta

6 FAMILY HISTORY OF BREAST CANCER
PAGKAKAROON NG KANSER SA SUSO SA PAMILYA

6.1 Did your mother ever have a diagnosis of breast cancer?.....1=yes...2=no.....|_|
 Nagkaroon ba ng kanser sa suso ang inyong nanay? 1=oo 2=hindi

(If NO goto 6.2) (kung HINDI ang sagot - itanong ang 6.2)

6.1.1 What age was she when she had breast cancer? (99 if age not known).....|_|
 Ilan taong guland and inyong nanang noong nagkaroon siya ng kanser sa suso? (99 kung hindi alam)

6.1.2 Is your mother alive?.....1=alive.... 2=dead.... 3=unknown.....|_|
 Bhay pa ba ang inyong ina? 1=buhay 2= patay 3=hindi alam

6.1.3 What age is/was she when she died ? (99=unknown).....|_|
 Ilan taong gulang ang inyong nanay ?(ngayon/noong namatay) (99=kung hindi alam)

6.2 How many sisters do/did you have? (0=no sisters).....|_|
 Mayroon ba kayong mga kapatid na babae? Kung mayroon, ilan sila (0 = kung wala)

If NONE, go to 6.3 Kung WALA ang sagot -----Itanong ang 6.3

6.2.1 Have any of them had breast cancer?.....1=yes...2=no.....|_|
 May isa ba sa iyong mga kapatid na babae ang nagkaroon ng kanser sa suso?....1=oo....2=hindi

6.3 How many brothers do/did you have? (0=no brothers).....|_|
 Mayroon ba kayong mga kapatid na lalake? Kung mayroon, ilan sila? (0 =kung wala)

If NONE, go to 6.4 Kung WALA ang sagot -----Itanong ang 6.4

6.3.1 Have any of them had breast cancer?.....1=yes...2=no.....|_|
 May isa ba sa kanila ang nagkaroon ng kanser sa suso?.....1=00....2=hindi

6.4 How many daughters do/did you have? (0=no daughters)|_|
 Mayroon ba kayong mga anak na babae? Kung mayroon, ilan sila (0 = kung wala)

If NONE, go to 7.1 Kung WALA ang sagot - Itanong ang no 7.1

6.4.1 Have any of them had breast cancer?.....1=yes...2=no.....|_|
 May isa ba sa kanila ang nagkaroon ng kanser sa suso?.....1=oo....2=hindi

7 PAP TESTS PAP SMEAR TESTS

7.1 Have you ever had a Pap smear in your life?.....1=yes.....2=no.....|_|
 Nagpasilip na ba kayo sa puwerta at nag-papap-smear?.....1=oo.....2=hindi

Make sure that the interviewee knows what a Pap smear is
Seguraduhing alam ng pasyente kung anong ibig sabihin ng pap smear

if NO, go to 8.1 Kung HINDI ang sagot - Itanong and no. 8.1

7.2 How many pap smears have you had in your life?.....|_|
 Ilan na bang pap smear ang naisagawa sa inyo?

7.3 At what age you had the first one?.....|_|
 Ilan taong gulang ho ba kayo noong ginawa ang pinakauna ninyong pap smear?

7.4 At what age you had the last one?.....|_|
 Ilan taong gulang ho ba kayo noong ginawa ang pinakahuli ninyong pap smear?

8 SELF-REPORTED ANTHROPOMETRIC MEASURES / TAAS AT TIMBANG NG PASYENTE

- 8.1 What is your height?.....|_|_|
Ano po ang taas ninyo? feet inches
- 8.2 What is your weight? (lbs).....|_|_|
Ano po ang timbang ninyo? (lbs)
- 8.3 When you were a girl, before you had your first menstruation, would you describe your weight as
1=less than 2= more than or 3= similar to that of the majority of your friends?.....|_|
Noong bata pa kayo, bago kayo nagkaroon ng regla, ang timbang kaya ninyo ay
1=mas mababa 2=mas mataas o 3=halos pareho lang--sa nakararami ninyong kaibigan?

9 PREVIOUS EXAMINATIONS OF THE BREASTS / MGA NAKARAANG EKSEMEN SA INYONG SUSO

- 9.1 Have you ever been examined by a doctor, in a Hospital or Health Centre for any breast complaints?
1=yes.....2=no.....3=Don't remember|_|
Naeksamen na ba kayo sa ospita, klinik, o health center nang dahil sa ano mang problema sa suso?
1=oo.....2=hindi.....3=hindi Maalala

(If NO, the questionnaire is finished)

(Kung HINDI, itanong ang

- 9.1.1 Have you ever had a diagnosis or biopsy of breast lump?
(Check breasts for scars needle point or incision).....1=yes.....2= no.....9= unknown.....|_|

Nagkaroon na ba kayo ng biopsy o operasyon sa suso na napatunayan sa ospital?
(Tingnan kung may hiwa o peklat sa suso).....1=oo.....2=hindi..9=hindi alam

- 9.1.2 Kailan ang huling papatingin ninyo sa doktor o ospital dahil sa problema sa suso gaya ng bukol sa suso

Araw____Buwan____Taon____
Pangalan ng ospital or klinik o health center:_____
Address: _____
Pangalan ng doktor: _____
Sabihin kung anong klaseng problema sa suso : _____

If YES, fill in the forms BBD for benign breast disease

This is the end of the Questionnaire. Thank you very much for your time and cooperation.
Now I would like to examine your breasts and show you how to practice it yourself.

Ito na po ang kahuli-huliang pagtatanong. Maraming salamat po sa inyong oras at tulong. Ngayon, puwede po bang masuri ang inyong suso at ituro ko rin sa inyo and paraan sa pansariling pagsusuri ng inyong suso (Breast Self-Examination or BSE)-----Fill up Form E (Breast Examination Form).

Grant No. DAMD17-94-J-4327

Appendix 2

Documentation of results for hospital clinics for referral of positive women.

FORM Pr

FORM 11 BREAST CANCER SCREENING PROJECT

SUBJECT POSITIVE AT BREAST EXAMINATION

Today's Date:

Day /_/_/- Mon /_/_/- Yr /_/_/

Study ID Number:

[illegible]

Mun'ty B'gay HS Record No. from pop'n list

Family Name of Subject:

Initials /_/_/-/_/_/-/_/_/

Referral Center: 1- JRRMMC 2- PGH 3- RMC 4- others, specify _____

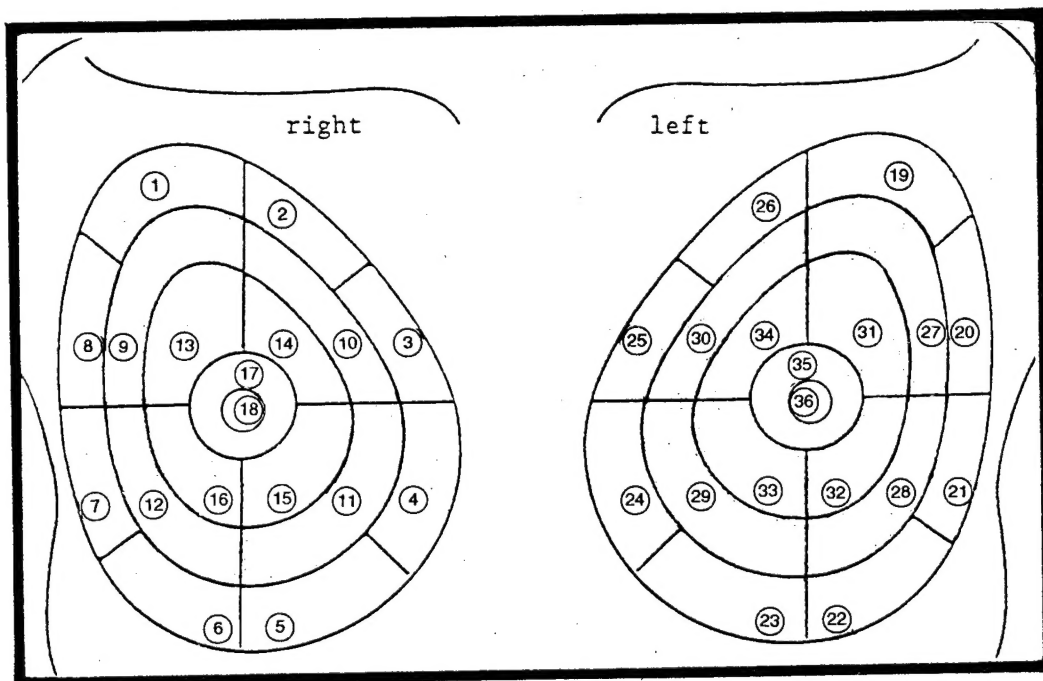
Visit Number:

11
111

Examiner:

14

Indicate laterality, location, size, mobility of the breast abnormalities below. Use graph numbers to identify lump in the describing



Lump No. /_/_/_/

Size: maximum Ø in cm.,

9= more than / = 9 cm..... / __/

Mobility: 1=mobile... 2=fix..... / __/

Hardness: 1=stone... 2=???.... 3=soft..... / _/

Lump No. / /

Size: maximum Ø in cm.,

9 = more than \neq 9 cm..... / _ /

Mobility: 1=mobile... 2=fix..... / _/

Hardness: 1=stone... 2=???.... 3=soft..... / _/

Lump No. /_/_/_

Size: maximum Ø in cm.,

9 = more than \geq 9 cm..... / _ /

Mobility: 1=mobile... 2=fix..... / _/

Hardness: 1=stone... 2=???.... 3=soft..... / _/

Lump No. / /

Size: maximum Ø in cm.,

9= more than / = 9 cm..... / __/

Mobility: 1=mobile... 2=fix..... / __/

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Lump No. / /

Size: maximum Ø in cm.,

9 = more than / = 9 cm..... / _

Mobility: 1=mobile... 2=fix..... /

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Lump No. /_/_/_

Size: maximum Ø in cm.,

9 = more than / = 9 cm..... /

Mobility: 1=mobile... 2=fix..... /

Hardness: 1=stone... 2=???.... 3=soft..... / _/